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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,271	12/12/2003	Tomomi Sugiyama	11333/31	3598
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			EXAMINER WRIGHT, PATRICIA KATHRYN	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 06/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/735,271

Applicant(s)

SUGIYAMA, TOMOMI

Examiner

P. Kathryn Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/2006;5/2004</u> .   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of group I (claims 1-19) in the reply filed on May 15, 2007 is acknowledged.

***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "management apparatus", "control means", "storage means", "analyzer identification information", and the "terminal device" in claims 5 and 15 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because Fig. 3 should include reference numbers which correspond to the description, e.g., "arrival confirmation input screen", "received sample number field", etc. Similarly, Figs. 5 and 6 do not include reference numbers that correspond to the container, barcode, required fluid quantity, etc. Correction is required.

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

**Specification**

6. The abstract of the disclosure is objected to. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

**Claim Rejections - 35 USC § 112**

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 recite a "storage means for storing" and a "control means for correcting". Both limitations use the language "means for". Furthermore, the "means for" is not modified by sufficient structure, material or acts for achieving the specified function. Thus, these claim limitations are being treated by the Office under 35 U.S.C. 112, sixth paragraph. Where means plus function language is used to define the characteristics of a machine or manufacture invention, such language *must be interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof" that correspond to the recited function*. However, the specification fails to set forth an adequate disclosure showing what is meant by the means plus function language. Specifically, what do the "storage means for storing" and the "control

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means for correcting” correspond to in the specification? Does the storage means for storing correspond to a database? Does the control means correspond to a computer? Since applicant failed to set forth an adequate disclosure, applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.

Furthermore, claims 1 and 12 recite a management apparatus comprising *inter alia*, an analyzer identification information for identifying whether or not the analyzer for the assay has a dilution mode. The specification does support a bar code *on the sample container* which indicates the type of analyzer used at page 19, lines 2-5. However, the specification does not disclose what the “analyzer identification information” corresponds to. Thus, it is unclear and confusing what Applicant is referring to. Clarification is required.

Claim 7, recites wherein the quantity of sample used in the assay is not input from the terminal device. This is confusing and indefinite since claim 7 depends from claim 5 which indicates the quantity of same used in the assay is input by the terminal device.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1 107 159 to Okuno et al., (hereinafter “Okuno”).

Okuno teaches a clinical laboratory management system comprising a plurality of analyzers 2 for analyzing samples and a management apparatus connected to the analyzers (see Fig. 1). The management apparatus of Okuno comprises a storage means 14 (e.g., database). Each of the analyzers of Okuno include control units 28 which acquires information from a control device 1 via network 3 (claims 11 and 19). This information includes an analyzer device ID that identifies the analysis device in the system [see par. 0133].

With respect to claims 5 and 15, the storage means 14 of Okuno is connected to a terminal device (e.g., personal computer, workstation; see par. [0069]) for information input. The quantity of sample used in the assay can be input by the terminal device. Regarding claims 8, 9, and 18 the management system 1 is connected to a printing device (see par. [0027]). With respect to claim 10, the sample identification information is printed as a bar code (see par. 0091)).

While the storage means 14 of Okuno is used to store analyzer identification information, the storage means is not used to store information that specifically indicates whether or not the analyzer used for assay has a dilution mode or the diluted sample identification information. However, such limitations are merely an intended use which Okuno would inherently be capable of doing. Moreover, the storage means of Okuno is "capable of" storing a dilution rate of the sample.

Likewise, the control means of Okuno is "capable of" correcting the result of the based on the dilution rate (see claims 3 and 13) and correcting the result when the

analyzer used in the assay does not have a dilution mode, and the sample used in the assay is a diluted sample, as set forth in claims 1 and 12.

Furthermore, the recitation of “when the analyzer...” in claims 1 and 12 is a conditional phrase that does not provide any additional structure to the apparatus, and therefore, does not limit the scope of the claim. Similarly, claims 7 and 17 both recite “when the quantity of sample used...when calculating the dilution rate”, this too is conditional and does not limit the scope of the claim.

The only distinction between Applicant’s claims and the prior art is recited functional language. A recitation of function may not distinguish over the prior art reference since an apparatus claim covers *what a device is, not what it does*. (Emphasis added.) Thus, it is incumbent upon Applicant to show that the application disclosed by the prior art is not actually capable of performing such functions. See *In re Ludtke*, 169 USQ 563 (CCPA 1971).

Note that the “wherein clauses” of claim 2, i.e., the first analyzer has a dilution mode, and wherein the second analyzer does not have a dilution mode, do not limit the claim to a particular *structure*. Thus, the wherein clause does not limit the scope of the claim.

While the printing means of Okuno is not used to output the dilution rate (claims 8 and 18) and the sample identification information (claim 9), such limitations are merely an intended use which Okuno would inherently be capable of doing. Again, it is incumbent upon Applicant to show that the application disclosed by the prior art is not actually capable of performing such functions.



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**Conclusion**

11. No claims allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 29, 2007  
pkw

  
Jill Warden  
Supervisory Patent Examiner  
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